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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/376,604	08/18/1999	RAGUPATHY MADIYALAKAN	AREX-P03-004	6693

7590 07/29/2005

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EXAMINER	
NICKOL, GARY B	
ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 07/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/376,604	MADIYALAKAN ET AL.	
	Examiner	Art Unit	
	Gary B. Nickol Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 May 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) *243,244 and 247-250* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *See Continuation Sheet* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

5.00

Re: Madiyalakan *et al.*

Date of priority: 06-17-1999

Response to Amendment

The Amendment filed 05-16-2005 in response to the Office Action of 11-16-2004 is acknowledged and has been entered.

New claims 258-273 were added.

Claims 113, 117-120, 123, 125, 129-135, 137-139, 141-144, 170-174, 180-182, 185, 187, 190-195, 197-204, 206-209, 235-239, 241-244, 247-250, 251, 254-273 are pending.

Claims 243-244, 247-250 have been withdrawn from further consideration by the examiner under 37 CFR 1.142(b) as being drawn to non-elected inventions.

Claims 113, 117-120, 123, 125, 129-135, 137-139, 141-144, 170-174, 180-182, 185, 187, 190-195, 197-204, 206-209, and 235-239, 241-242, 251, 254-273 are currently under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Rejections Maintained:

Claims 113, 117-120, 123, 131-135, 137-139, 141-144, 170-174, 180-182, 185, 190, 193-195, 197-204, 206-209, 235-239, 241-242, and 251 remain rejected **and** new Claims 260-261, 264-265, 268-269, 272-273 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent No. 5,532,159 (Webb *et al.* April 1, 1994) for the reasons of record.

With regard to new claims 260-261, 264-265, 268-269, 272-273, Webb *et al.* teach the administration of non-human, murine monoclonal antibodies (column 9, line 12)

Applicants continue to traverse the Examiner's rejection over the cited prior art of Webb reiterating that Webb's particular belief (i.e., Webb believes that OFP is immunosuppressive and that by sequestering or removing the tumor antigen with monoclonal antibodies, a patient's immune defense against tumors is released from impairment which allows for a more efficient and natural rejection of cancer.) renders the claims non-anticipatory. Applicants argue (Response, page 13) that because of Webb's belief and because Webb's anti-tumor response only occurred within one day (emphasis added) after the administration of one dose of the anti-OFP antibody, there is no evidence that the method disclosed by Webb induces a host immune response against the OFP/antibody complex, including T-cell and B-cell (humoral) immune responses.

However, as these arguments have been presented earlier they are not found persuasive for the reasons of record (Action mailed 11-16-2004). Moreover, applicants own specification (page 13, line 25+) also suggests that the claimed mechanism of the invention is *not* bound by an particular theory of operability. Like Webb *et al.*, Applicants "believed" that the observed immunological response is attributable to an interaction between a newly formed antigen and the human pateint's immune system.

Applicants further reiterate the Examiner's rebuttal mailed 03-15-2004 in presenting their case. (Brief, page 15). Applicants argue that the Examiner's comments are insufficient, as a matter of law, to establish anticipation under a theory of inherency. This argument has been considered but is not found persuasive as the latter Action of 3-15-04 was made solely in response to applicant's arguments that followed the non-final rejection.

The fact of the matter is that this case is a model of inherent anticipation. Both the claimed invention and the prior art administer antibodies specific to a soluble tumor associated *self*-antigen (i.e., an antigen that on it own is incapable of eliciting an effective host immune response) for the purposes of treating cancer. Thus, while Webb *et al* do not characterize the immune response as eliciting a cell-mediated (T-cell) or humoral immune response, the claimed functional limitation would be an inherent property of the referenced method because it does not appear that the claim language or limitation results in a manipulative difference in the method steps when compared to the prior art disclosure. See Bristol-Myers Squibb Company v. Ben Venue Laboratories 58 USPQ2d 1508 (CAFC 2001).

Hence, even though the claims are inclusive of what happens in the body, the claimed method does not appear to distinguish over the prior art teaching of the same or nearly the same method. *The mechanism of action does not have a bearing on the patentability of the invention if the invention was already known or obvious*. Mere recognition of latent properties in the prior art does not render nonobvious an otherwise known invention. In re Wiseman, 201 USPQ 658 (CCPA 1979). Granting a patent on the discovery of an unknown but inherent function would remove from the public that which is in the public domain by virtue of its inclusion in, or obviousness from, the prior art. In re Baxter Travenol Labs, 21 USPQ2d 1281 (Fed. Cir. 1991).

See M.P.E.P. 2145. Thus, applicant's arguments have not been found persuasive and the rejection is maintained.

Claims 125, 129-130, 187, 191-192, 254-257 remain rejected **and** new claims 258-259, 262-263, 266-267, 270-271 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baum *et al.* (Hybridoma, Vol. 12, No. 5, 1993, pages 583-589) **or** Madiyalakan *et al.* (Hybridoma, Volume 14, No. 2, May 19, 1995) in further view of US Patent No. 5,532,159 (Webb *et al.* April 1, 1994) for the reasons of record.

Applicants argue that there is no motivation to combine the teachings of Webb, Baum and Madiyalakan. Applicants argue that both Baum and Madiyalakan teach the use of "radiolabeled" antibodies wherein the radionuclide is the toxic agent, and that the antibody or antibody fragment is merely a targeting mechanism, not the basis for the therapeutic treatment. These arguments have been carefully considered but are not found persuasive for the reasons of record in the Action mailed 03-15-2004, pages 4-5. Thus, applicant's arguments have not been found persuasive, and the rejection is maintained.

Additionally, with regards to new claims 258-259, 262-263, 266-267, 270-271, Madiyalakan *et al.* teach administering the composition at least two times in a human host (page 200).

Claims 190, and 238 remain rejected **and** new Claims 260, 264, 268, and 272 are rejected under 35 USC 112, first paragraph, as the specification does not contain a written description of the claimed invention. The limitation of an antibody which is "non-human" (Claim 190) has no

clear support in the specification and the claims as originally filed. Applicants appear to argue (Response, page 17) that since they've disclosed a murine monoclonal antibody (B43.13), they've meet the written description of a "non-human" antibody. Applicants argue that the subject matter of the claimed invention need not be described literally. This argument has been considered but is not found persuasive because although a murine antibody is non-human, the claims are broadly drawn to a genus of "non-human" antibodies which is much broader in scope than murine antibodies. For example, this could include other mammalian antibodies such as rabbit, guinea pig, and dog antibodies. Thus, applicant's claiming of murine antibodies is insufficient to meet the broader scope of all non-human antibodies and the new matter rejection is maintained. Applicant is required to cancel the new matter in the response to this Office Action. Alternatively, applicant is invited to provide sufficient written support for the "limitation" indicated above. See MPEP 714.02 and 2163.06.

No claim is allowed.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary B. Nickol Ph.D. whose telephone number is 571-272-0835. The examiner can normally be reached on M-Th, 8:30-5:30; alternate Fri., 8:30-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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GBN

GARY B. NICKOL, PH.D.
PRIMARY EXAMINER